

## **202 KAR 4:010. Spinal Cord and Head Injury Research Program.**

RELATES TO: KRS 189.125, 189.394(5), 211.504

STATUTORY AUTHORITY: KRS 211.500, 211.502, 211.504

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.502 provides that the Kentucky Spinal Cord and Head Injury Research Board promulgate administrative regulations necessary to review and authorize spinal cord and head injury research projects and programs, pursuant to the provisions of KRS 211.500 to 211.504. This administrative regulation establishes the protocol by which the Kentucky Spinal Cord and Head Injury Board will review research grant proposals from the University of Kentucky and the University of Louisville. It further establishes the guidelines by which grant proposals from the universities are rated and the mechanism by which funds are allocated for the appropriate grants proposals.

Section 1. Definitions. (1) "APA" means the American Paralysis Association.

(2) "Applicant" means the entity within the University of Kentucky or University of Louisville applying for the grant award.

(3) "Board" means the Kentucky Spinal Cord and Head Injury Research Board.

(4) "Host institution" means the University of Kentucky or the University of Louisville.

(5) "NIH" means the National Institutes of Health.

(6) "PI" means the principle investigator.

(7) "SAC" means the Science Advisory Council of the American Paralysis Association.

(8) "Trust" means the Kentucky Spinal Cord and Head Injury Trust.

Section 2. Proposal Submission Process. (1) A research project proposal shall be submitted to the board on "Proposal Application and Instructions" form.

(2) The submission deadline for research proposal applications shall be September 30 of each year.

(3) The board shall transmit a project proposal to the director of research with a request that he transmit the:

(a) Project proposal to the members of the SAC of the APA for their review; and

(b) Rating recommendations for each project made by the members of the SAC to ~~the board~~ the board

(4) After review of the rating recommendations submitted to the board, the board shall determine whether a project proposal shall be funded.

(5) An applicant shall be notified of the board's decision by December 31 of each year.

Section 3. Project Proposal Review Criteria. (1) A project proposal shall be reviewed by the board for scientific merit and adherence to the research priorities established by subsections (2) and (3) of this section.

(2) A project proposal shall be reviewed for scientific merit as follows:

(a) Adequacy of prior research and theory in providing a basis for the research;

(b) Adequacy of methods;

(c) Adequacy of environment, facilities, equipment, available expertise, research atmosphere;

(d) Qualifications and productivity of the PI and his key staff;

(e) Time commitments of the PI and his key staff;

(f) Availability of subjects or patients where relevant;

(g) Adequacy of procedures for assessing the effect of interventions on recovery; and

(h) Other factors that affect the potential of the applicant to address successfully the research aims.

(3) A project proposal shall be reviewed by the board for adherence to research priorities as fol-

lows:

- (a) In vivo and in vitro studies on naturally occurring phenomena that may:
  - 1. Promote neuronal growth;
  - 2. Encourage the formation of synapses;
  - 3. Enhance the production of myelin;
  - 4. Restore conduction capabilities; or
  - 5. Otherwise lead toward restoring compromised circuitry in the injured spinal cord or brain.
- (b) Evaluation of the efficacy of pharmacological agents or other interventions that:
  - 1. Protect against secondary neuronal injury;
  - 2. Improve function in chronic spinal cord or brain injury; or
  - 3. Provide insight into the mechanisms causing such damage.
- (c) Biological characterization of spinal cord or head injury in well-defined animal models, and in the human spinal cord or brain, specifically documenting the neuronal systems that are most vulnerable to the functional losses that occur as a result.
- (d) Development of new and more sensitive approaches for evaluating recovery after injury.

Section 4. Research Grantee Responsibilities. (1) A research contract shall be granted for a three (3) year period subject to the conditions established by this section. Renewal in years two (2) and three (3) shall depend upon fulfillment of contract terms.

(2) A grantee shall submit to the board an annual progress report, including a narrative and financial report of his progress.

(3) The annual progress report shall be due sixty (60) days prior to the anniversary of the contract start date.

(4)(a) A grantee shall submit a final:

- 1. Narrative progress report thirty (30) days after completion or termination of the contract; and
- 2. Financial report no later than ninety (90) days after completion or termination of the contract.

(b) The financial report shall be completed by the office of grants and contracts of the contracting institution.

(5) The PI shall transmit to the board copies of publications that emerge as a result of the funded research, during and after the period of the contract.

(6) A grantee shall acknowledge the source of funding from the trust in all publications and presentations.

Section 5. Incorporation by Reference. (1) "Proposal Application and Instructions KSB 8/95" is incorporated by reference.

(2) This form may be inspected, copied, or obtained at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky, 8 a.m. to 4:30 p.m., Monday through Friday. (22 Ky.R. 1747; Am. 2288; eff. 6-6-96.)